

"If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." (MPEP § 803, emphasis added).

In the Office Action, the Examiner divided and characterized the claims of the application into seven groups (p. 2 of the Office Action):

- Group 1: Claims 1-29 as drawn to an isolated MUC-1 specific binding domain;
- Group 2: Claims 30-54 as drawn to polynucleotide host cell and vectors;
- Group 3: Claims 55-58 as drawn to a method of diagnosing cancer;
- Group 4: Claims 59-67 as drawn to a method of treating cancer; and
- Group 5: Claims 68 and 69 as drawn to a method of making the MUC-1 binding domains

For the record, Applicants note that the description of the proposed restriction groups mischaracterizes the nature of a number of the claims. A person skilled in this art who reads the specification will find clear definitions and explanations of various terms used to describe and claim the invention. See, e.g., p. 10, line 19-p. 16, line 28 of the specification. Accordingly, a more accurate description is that Claims 1-29 are directed to various novel MUC1-specific binding members and polypeptides, which comprise particular binding domains for MUC1. In addition, Claims 30-54 are not directed to host cells, but to polynucleotide molecules, which comprise nucleotide coding sequences for the novel MUC1-specific binding polypeptides of the invention. Finally, Claims 68 and 69 are directed to methods of making novel MUC1-specific binding members of the invention.

The Examiner provided reasons for dividing the claims into the above restriction groups such as unrelated molecules (e.g., polypeptide versus polynucleotide); unrelated process steps (e.g., methods of using versus methods of making MUC1-specific binding members); and unrelated subjects (e.g., methods versus products). See, paragraphs 1-6 in the Office Action. Applicants respectfully traverse the purported restriction requirement of the pending claims as well as any election of species for the reasons set forth below.

Applicants note that the glycoprotein mucin-1 (MUC1) has become an intensively studied target molecule associated with cancers, such as adenocarcinoma of blood, breast, and ovary. Applicants' invention is based on the discovery of a group of novel MUC1-specific binding members, including antibody molecules and portions thereof, such as the PH1 Fab antibody. For example, the PH1 Fab antibody comprises the amino acid sequence of SEQ ID NO:1 of the variable light chain (V_L) region and the amino acid sequence of SEQ ID NO:3 of the variable heavy chain (V_H) region, including framework and hypervariable regions, i.e., the complementarity-determining regions (CDRs) thereof (see, e.g., p. 17, line 1-p. 18, line 29 of the specification). Other MUC1-specific binding members are also described (see, e.g., p. 18, line 31-p. 23, line 24). A description of a novel class of MUC1-binding members of the invention comprises a binding domain having the amino acid sequence of SEQ ID NO:28 (see, e.g., p. 23, line 25-p. 24, line 1 of the specification). Applicants' disclosure also clearly describes the use of such sequences, to prepare and use any of a variety of MUC1-specific binding members, including full-length immunoglobulins, Fab antibodies, F(ab')₂ antibodies, diabodies, single chain antibodies (scFv), Fv molecules, and MUC1-specific fusion proteins, such as immunocytokines (see, e.g., Example 1, p. 32, line 20-p. 44, line 20 of the specification). Thus, the inventive feature of the claims is a class of novel MUC1 binding members and methods comprising or encoding such novel molecules.

The Examiner also stated that Applicants must elect a single disclosed species for certain claims of the proposed restriction groups (see, p. 2 of the Office Action). Applicants note that the list only mentions several sequences or portions of sequences that form a *part* of a claimed MUC1-specific binding member or polynucleotide encoding the same. Since, as noted above, Applicants do not believe a restriction of the claims is required, neither is an election of species, as a search of all claims would be not place a serious burden on the Examiner.

The above comments show that all of the claims share the same, key inventive feature of comprising a class of heretofore unknown, MUC1-specific binding members, or nucleotide sequences encoding such members. Applicants respectfully submit that a search of the art relating to any of the restriction groups would reveal all the art relevant to the other groups, and therefore examination of the subject matter of all the claims together would not place a serious burden on the Examiner. Accordingly, restriction of the claims and an election of a particular

species for the claims is unnecessary and improper according to procedural practices promulgated by the Patent Office (MPEP § 803).

Although Applicants believe that restriction of the claims and election of a species is improper, without in any way acquiescing or conceding to the reasons for the restriction requirement set forth in the Office Action, but in order to be fully responsive to the Office Action, Applicants provisionally elect for examination the claims of Group I (Claims 1-29). Likewise, with respect to selecting particular species within claims of Group I, based on the options provided by the Examiner at paragraph 8.a.-c. of the Office Action and to be fully responsive, Applicants provisionally elect the following species:

In the formula of SEQ ID NO: 28 (Claim 1), the species where X₁ is Ala, X₂ is Lys, X₃ is Gly, X₄ is Asp, X₅ is Ile, X₆ is Asp, X₇ is Tyr. That is, the species characterized by the amino acid sequence Ala-Lys-His-Thr-Gly-Gly-Gly-Val-Trp-Asp-Pro-Ile-Asp-Tyr (e.g., amino acids 97-110 of SEQ ID NO:3). Claims 1-29 are readable on the elected species.

Respectfully submitted,



Leon R. Yankwich (Reg. No. 30,237)
 Thomas R. Berka, Ph.D. (Reg. No. 39,606)
 Attorneys for Applicants
 YANKWICH & ASSOCIATES
 130 Bishop Allen Drive
 Cambridge, Massachusetts 02139
 telephone: (617) 491-4343
 telefax: (617) 491-8801

CERTIFICATE OF EXPRESS MAILING

The undersigned hereby certifies that this correspondence is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service, under 37CFR1.10, in an envelope addressed to the Commissioner for Patents, Washington, DC 20231, on the date indicated below.

Express Mail Label No.: **EL909962703US**

July 30, 2002
 Date of mailing and signature


 Melanie A. McFadden